PATENT ABSTRACTS OF JAPAN

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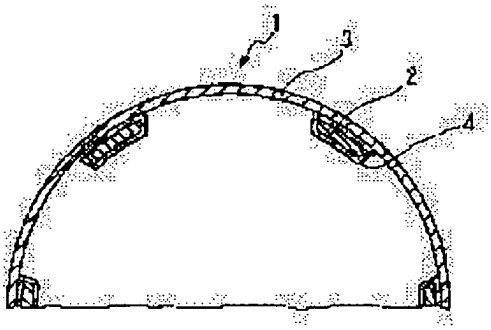
(54) STENT FOR IN-VIVO INDWELLING

(57)Abstract:
PURPOSE: To provide a stent for in-vivo indwelling which has stent bodies and a cover for cladding the sidewalls of these stent bodies and is capable of maintaining the fixed state of both over a long period of time without allowing the cover to hinder the deformation of the stent bodies at the time of such deformation and without allowing the cover to be detached from the stent bodies.
CONSTITUTION: This stent 1 consists of the stent bodies 2 which are formed to an approximately cylindrical shape, have apertures and are shrinkable in diameter and the cylindrical cover 3 which clads the stent bodies 2. The front surfaces of the stent bodies 2 are covered by thermoplastic resins 4. The cover 3 and these thermoplastic resins 4 are thermally fused in the contact parts of both.



CLAIMS

[Claim(s)]
[Claim 1]Stent for detention in the living body characterized by comprising the following.
A stent body in which it was formed in the shape of a cylindrical shape, and two or more openings which open an outside surface and an inner surface of this cylindrical shape for free passage were formed and whose diameter can be reduced.
A thermoplastic resin layer which covers this stent body.
A cylindrical cover which adhered to this thermoplastic resin layer while covering a periphery and/or inner circumference of this stent body and plugging up this opening.

[Claim 2]The stent for detention in the living body according to claim 1 in which some thermoplastics in which said cylindrical cover is formed in of a porosity film, and this cylindrical cover and said thermoplastic resin layer form a thermoplastic resin layer is flowing in fine pores of said porosity film.
[Claim 3]Stent for detention in the living body having the following, and at least one side of this inner surface side film and this outside surface side film serving as a tube-like object, and having pinched said stent body further between this inner surface side film and this outside surface side film, and having adhered through this opening.
A stent body in which it was formed in the shape of a cylindrical shape, and two or more openings which open an outside surface and an inner surface of this cylindrical shape for free passage were formed and whose diameter can be reduced.
The inner surface side film with which it is the stent provided with a cylindrical cover which plugs up this opening and wraps this stent body entirely, and said cylindrical cover was provided in said stent body inner surface.
The outside surface side film provided in the outside surface side of said stent body.

[Claim 4]The stent for detention in the living body according to claim 3 in which both said inner surface side film and said outside surface side film are tube-like objects.
[Claim 5]Said inner surface side film or said outside surface side film at least either, Are a layered product of the 1st resin layer and the 2nd resin layer formed with resin whose melting point is lower than the 1st resin layer formation resin, and another side of said inner surface side film or said outside surface side film, The stent for detention in the living body according to claim 3 or 4 currently formed with a resin film in which said 2nd resin layer and thermal melting arrival are possible.
[Claim 6]Said inner surface side film and said outside surface side film, the 1st resin layer -- this -- the stent for detention in the living body according to claim 3 in which thermal melting arrival of both is carried out after it was formed of a layered product with the 2nd resin layer formed with resin whose melting point is lower than the 1st resin layer formation resin and each 2nd resin film has faced each other.

[Translation done.]

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Industrial Application]This invention relates to the stent for detention in the living body used for the improvement of the narrow segment produced in the living body, such as an organ of a blood vessel, a bile duct, a trachea, an esophagus, an urethra, and others.
[0002]
[Description of the Prior Art]Conventionally, it inserts in the narrow segment of living body lumina, such as an organ of a blood vessel, a bile duct, an esophagus, a trachea, an urethra, and others, or the abdominal cavity, and various stent for securing a lumen or abdominal cavity space is proposed.
[0003]The stent is distinguished by the self expander bull stent and the balloon expander bull stent by the function and the detention method. In order for expanded function not to have the balloon expander bull stent in the stent itself and to detain the stent in a target part, After inserting the stent in a target part, extend the balloon located in the stent, the stent is made to expand with the extension power of a balloon (plastic deformation), and adhesion immobilization is carried out at the inner surface of a target part. Therefore, in this type of stent, expansion of the above stent is needed.
[0004]As for the self expander bull stent, the stent itself has contraction and expanded function. After inserting in a target part where the stent is shrunk in order to detain the stent in a target part, the stress which carried out load for maintenance of a contracted state is removed. For example, after shrinking the stent in the tube of an outer diameter smaller than the inside diameter of a target part, storing and making the tip of this tube arrive at a target part, it is carried out by extruding the stent from a tube. By being released from a tube, stress load is canceled, and the extruded stent is restored and extended to the shape before contraction. This sticks and fixes to the inner surface of a target part. In this type of stent, the expansion like the balloon expander bull stent is unnecessary, and the technique is easy for it.
[0005]Various things are proposed as such self expander bull stent. These days, in order to prevent the restenosis of the blood vessel by the organization which invaded from between the wire supports of the stent, what provided covering which has pliability is proposed. As stent which has such covering, there are some which are shown in JP,4-263852,A, for example. The stent is surrounded in the stent assembly currently indicated by JP,4-263852,A by the sleeve (covering) which has pliability. The stent which has covering also in JP,2-174859,A is indicated. Also in this stent assembly, the wall surface is covered thinly and highly with the elastic tunic by the business to which the stent does not block a request extension and modification of the stent.
[0006]
[Problem(s) to be Solved by the Invention]In the thing of above-mentioned JP,2-174859,A, it is only arranging the tunic to the stent and both are not combined. For this reason, when detaining in the living body, there is a possibility that the stent may break away from a tunic. The stent breaks away from a tunic also after detention, and there is a danger that the stent will move from a target part. It is indicating suturing pasting up the stent on a sleeve (covering), or embedding as a fixing method of the stent and covering, at JP,4-263852,A. However, in a suture, since it is only physical ligation power, junction power is weak, when the diameter of the stent is made to reduce before detention work, there is a danger that both suture will separate, and there is a danger that both suture will separate also after the time of detention work and detention. In the case where the stent is embedded to a sleeve, only the portion (near the support of the stent) and sleeve which were embedded have a large change of the physical properties in a portion, and have the danger that a sleeve will fracture by both boundary part.

[0007]The purpose of this invention provides the stent which canceled the problem of the above-mentioned conventional technology. It is the stent which has covering which specifically wraps entirely the side attachment wall in which the stent body and the stent body carried out the opening, It does not become an obstacle substantially [modification / covering / a stent body], and covering does not break away easily from a stent body, and the stent for detention in the living body which can maintain both fixed state in the long run is provided.

[0008]

[Means for Solving the Problem]A stent body in which what attains the above-mentioned purpose was formed in the shape of a cylindrical shape, and two or more openings (or hole) which open an outside surface and an inner surface of this cylindrical shape for free passage were formed and whose diameter can be reduced, While covering a thermoplastic resin layer which covers this stent body, and a periphery and/or inner circumference (or a peripheral face and/or inner skin) of this stent body and plugging up this opening (or hole), It is the stent for detention in the living body provided with a cylindrical cover which adhered to this thermoplastic resin layer.

[0009]A stent body in which in other words this stent was formed in the shape of a cylindrical shape and whose diameter can be reduced, It is the stent provided with a cylindrical cover which blocks a side attachment wall of this stent body (blockade), and the surface of said stent body is covered with thermoplastics, and said cylindrical cover and said thermoplastics have adhered in both contact portion.

[0010]said cylindrical cover has wrapped said stent body entirely from the outside, for example -- in other words, a peripheral face is wrapped entirely. said cylindrical cover has adhered to an inner surface of said stent body, for example -- in other words, inner skin is covered. Said cylindrical cover is formed of a porosity film made of resin, for example. It is preferred that both have adhered, when said some of thermoplastics flows in fine pores of said porosity film. Said porosity film is provided in a peripheral face of said stent body, for example. As for said thermoplastics, it is preferred that the melting point is lower than formation resin of said porosity film. Said thermoplastics and said porosity film have adhered by thermal melting arrival, for example. The diameter of it is reduced, for example until said stent body is inserted in a site of action in the abdominal cavity, and it is a thing of metal or resin extensible in a site of action. Said metal is superelasticity metal, for example. Said thermoplastics is a solvent meltable type fluoro-resin, for example.

[0011]A stent body in which what attains the above-mentioned purpose was formed in the shape of a cylindrical shape, and two or more openings (or hole) which open an outside surface and an inner surface of this cylindrical shape for free passage were formed and whose diameter can be reduced, Are a cylindrical cover which plugs up this opening (or hole) and wraps this stent body entirely the stent which it has, and said cylindrical cover, It consists of an inner surface side film provided in said stent body inner surface, and an outside surface side film provided in the outside surface side of said stent body, It is the stent for detention in the living body at least one side of this inner surface side film and this outside surface side film serving as a tube-like object, and having pinched said stent body further between this inner surface side film and this outside surface side film, and having adhered through this opening (or hole). In other words, are a stent body which was formed in the shape of a cylindrical shape and whose diameter can be reduced, and a cylindrical cover which wraps a side attachment wall (side) of this stent body entirely the stent which it has, and said cylindrical cover, It consists of an inner surface side film provided in an inner surface of said stent body, and an outside surface side film provided in the outside surface side of said stent body, It is stent for detention in the living body which has adhered in both contact portion while either [at least] this inner surface side film or this outside surface side film serves as a tube-like object and it pinches said stent body further by between this inner surface side film and this outside surface side film.

[0012]As for both said inner surface side film and said outside surface side film, it is preferred that it is a tube-like object. Said inner surface side film or said outside surface side film at least either, It is a layered product with the 2nd resin layer formed with resin whose melting point is lower than the 1st resin layer formation resin, and, as for another side of said inner surface side film or said outside surface side film, it is preferred to be formed with a resin film in which said 2nd resin layer and thermal melting arrival are possible. said inner surface side film and said outside surface side film -- the 1st resin layer -- this -- it is preferred that thermal melting arrival of both is carried out after it was formed of a layered product with the 2nd resin layer formed with resin whose melting point is lower than the 1st resin layer formation resin and each 2nd resin film has faced each other. Said inner surface side film or said outside surface side film is a PET (polyethylene terephthalate) film by which biaxial extension of said 1st resin layer was carried out, for example, and said 2nd resin layer is olefin system thermoplastics.

[0013]Stent of this invention is explained using an example shown in a drawing. Drawing 1 is a perspective view of one example of stent of this invention, drawing 2 is an amputation stump side figure near the end of stent shown in drawing 1, and drawing 3 is the elements on larger scale of drawing 2. The stent 1 of this example is provided with the following.
The stent body 2 which was formed in the shape of a cylindrical shape and whose diameter can be reduced.
The thermoplastic resin layer 4 which covers the stent body 2.
The cylindrical cover 3 which adhered to the thermoplastic resin layer 4 while blocking the side of the stent body 2.

[0014]Thus, a side attachment wall (a periphery, inner circumference, a peripheral face, or inner skin) of the stent body 2 covered with the thermoplastics 4 is entirely wrapped with the cylindrical cover 3, as shown in drawing 1 (blockade). For this reason, a free passage portion (hole) formed in stent side attachment walls, such as an opening of the stent body 2 and a notch, is that which is blocked with covering, and a body tissue prevents invading in stent from the exterior. Thermal melting arrival is carried out to the thermoplastics 4, the cylindrical cover 3 does not exfoliate from the stent body 2, and the cylindrical cover 3 prevents separation of both after the time of detention work of stent and detention.
[0015]The stent 1 is a tube-like object and has the open ends 1a and 1b to both ends. As for the stent 1, 2.0-30 mm, 2.5-20 mm and an inside diameter are 1.6-29.4-mm things preferably 1.4-29 mm, and length is 15-100 mm in an outer diameter more preferably 10-150 mm. As the stent body 2 is shown in drawing 1, it has two or more notch or two or more openings which were formed in the side of the cylinder body 2, and a modification auxiliary function which assists modification to a direction whose diameter an outer diameter reduces by this at the time of stress load is formed.
[0016]The stent body 2 is specifically a cylindrical frame without front fork, and has the notch 2d divided by the frame 2a, the opening (or hole) 2c divided with 2b (****), and the frame 2a. An end of a stent body is on one circle, it is constituted by aggregate of two or more not continuous circles, and they are carrying out equiangularity alienation mostly. If the notch 2d is not formed, an end of the stent body 2 is a round shape mostly, and forms two or more circles which carried out equiangularity alienation from the center of the stent body 2 by forming the notch 2d. The frame 2a is formed so that it may be extended aslant [predetermined angle] to a medial axis of the stent body 2. The two frames 2a which continue at the end form equilateral [of an isosceles triangle / two]. And the frame 2a of both ends is connected with frame 2b. Frame 2b is formed almost in parallel with a medial axis of the frame without front fork 2. In this example, frame 2b has a frame twice [about] the width of 2a. As shown in drawing 2 and drawing 3, as for [when it cuts in the direction which intersects perpendicularly with a medial axis of the frame 2a and a stent body of 2b] sectional shape, a top chord serves as a flabellate form whose side became a straight line with a circle with a circle in which a base is shorter than a top chord. An outside surface of a frame (stent body) is in the state where there is no edge and it cuted off the corners in the whole.
[0017]In this stent body 2, since it has a notch at the end, modification of an end of stent becomes easy, especially, partial metamorphosis of an end becomes possible and a response to the time of modification of a blood vessel detained becomes good. Since an end of a stent body is formed of an end of two or more frames 2a, it is not crushed easily and has sufficient intensity. Among both ends, the frame 2a and the opening 2c surrounded by 2b are formed, and this opening 2c changes easily according to modification of the frame 2a. For this reason, modification in that center section (center section of the frame without front fork 2) is easy for the stent body 2.
[0018]In this example, the opening 2c is carrying out a hexagon of shape pressed and crushed, and the notch 2d is carrying out an isosceles triangle. Six pieces are specifically formed and the notch 2d is each end with plurality and shape where each is almost equal. As the opening 2c also forms the side of the stent body 2, specifically, two or more six pieces are formed. A notch and an opening are not limited to above-mentioned shape and the number, and about 3-10 pieces are preferred for them as 3-10 pieces and an opening as a notch. In the stent body 2, it has shape where an above-shaped stent member was connected by the two articulated sections 2e.
[0019]A synthetic resin or metal is used as a formation material of a stent body. What has a certain amount of hardness and elasticity as a synthetic resin is used, and a biocompatibility synthetic resin is preferred. Specifically, they are polyolefine (for example, polyethylene, polypropylene), polyester (for example, polyethylene terephthalate), a fluoro-resin (for example, PTFE, ETFE), etc. What has biocompatibility also as metal is

preferred, for example, there are stainless steel, tantalum titanium, a nickel titanium alloy, etc. In particular, superelasticity metal is preferred. As for the stent body 2, being formed in one is preferred, without forming a rapid changed part of physical properties in the whole. A stent body prepares a metallic pipe which has the outer diameter which suited at least an inside of a living body detained, for example, removes the side of a metallic pipe selectively by those, such as cutting and chemical etching, and is created by forming two or more notch or two or more openings in the side.

[0020]As superelasticity metal which forms the stent body 2, a superelastic alloy is preferred. Generally a superelastic alloy here is called shape memory alloy, and shows superelasticity at living body temperature (near 37 **) at least. A Ti Ni alloy of 49-53 atom %nickel, Cu-Zn alloy of 38.5 to 41.5-% of the weight Zn, a Cu-Zn-X alloy (X=Be, Si, Sn, aluminum, Ga) of 1-10 % of the weight X, nickel-aluminum alloy of 36-38 atom %aluminum, etc. are used especially suitably preferably. It is the above-mentioned Ti Ni alloy especially preferably. What some Ti-Ni alloys are used as Ti-nickel-X alloys (X=Co, Fe, Mn, Cr, V, aluminum, Nb, W, B, etc.) replaced by X 0.01 to 10.0% for, Or a mechanical property is changeable suitably by choosing conditions of using some Ti-Ni alloys as a Ti-nickel-X alloy (X=Cu, Pb, Zr) replaced by an atom 0.01 to 30.0% and a cold working rate, or/and final heat treatment. A mechanical property is changeable suitably by choosing conditions of a cold working rate and/or final heat treatment using the above-mentioned Ti-nickel-X alloy.

[0021]And buckling strength (yield stress at the time of load) of a superelastic alloy used, 5-20kg[/mm] ^{2} (22 **) -- more -- desirable -- 8-150kg[/mm] ^{2} and restoration stress (yield stress at the time of unloading) -- 3-180kg[/mm] ^{2} (22 **) -- it is 5-130kg[/mm] ^{2} more preferably. Even if it changes superelasticity here to a field in which usual metal carries out plastic deformation at service temperature (bending tension, compression), it means recovering in the original shape mostly, without needing heating after release of modification.

[0022]And the stent body 2 is created by, for example, removing a portion used as a notch and an opening using a superelasticity metallic pipe (for example, cutting, the dissolution). According to this method, it really in which a changed part of rapid physical properties is not formed becomes a formation thing. When there is a rapid changed part of physical properties, the portion shows a different modification moving state from other portions. And there is a danger of metal stress starting a portion from which physical properties differed, and damaging from the portion. When a changed part of physical properties exists, modification as the whole stent becomes unnatural, a flow unnatural in the style of [which flows through an inside] blood is formed, and there is a danger of becoming a cause of strangulation again. However, since it is really in which a changed part of rapid physical properties is not formed in a stent body of this example formed with a formation thing, there are no above problems.

[0023]A superelasticity metallic pipe used for formation of the stent body 2, Dissolve in inactive gas or a vacuum atmosphere, form an ingot of superelastic alloys, such as Ti-Ni alloy, grind this ingot mechanically, and by then, hot pressing and extrusion. It can manufacture by narrow-diameter-izing to predetermined thickness and a pipe of an outer diameter, and carrying out chemical or physical polish of the surface eventually by forming a large diameter pipe and repeating a dice drawing process and a heat treatment process successively after that. And laser processing (for example, YAG laser), an electron discharge method, chemical etching, cutting, etc. can perform formation of a notch to this superelasticity metallic pipe, or two or more openings, and those concomitant use may perform further.

[0024]That the diameter can be reduced at the time of insertion, what is necessary is just to be able to expand the diameter of shape of the stent body 2 at the time of discharge in the living body (restoration), and it is not limited to above-mentioned shape. For example, a thing of a coiled thing, a cylindrical thing, a rolled form thing, a shape tube-like thing, a supercoil-like thing, a board spring coil-like thing, a basket, or mesh state may be used.

[0025]The stent body 2 is covered with the thermoplastics 4 as shown in drawing 2. As thermoplastics, a thermoplastic fluoro-resin, polyolefine. (For example, low density polyethylene and low density polypropylene), vinyl chloride resin, an ethylene-vinyl acetate copolymer, polyester (low melting point polyester), polycarbonate, ABS plastics, silicone rubber (RTV rubber), thermoplastic polyurethane, etc. can be used. And solvent meltable type thermoplastics is more preferred than workability and a point with easy uniform coating. As solvent meltable type thermoplastics, there are a fluorinated elastomer, an ethylene-vinyl acetate copolymer, vinyl chloride resin, silicone rubber (RTV rubber), polyurethane, etc. which are thermoplastics fluoro-resins. As thermoplastics, that whose melting point is about 120-200 ** is preferred, and about 10-100 micrometers is preferred as coating thickness of the thermoplastics 4.

0026]If it puts in another way so that the side (side attachment wall) of the stent body 2 may be blocked, the

cylindrical cover 3 is formed so that a periphery of the stent body 2, inner circumference, or its both may be closed. And it has adhered in the whole contact portion (contact portion with the thermoplastics 4) with the stent body 2. For this reason, the flattery nature of modification of covering to modification of a stent body is high, and it is rare for covering to become an obstacle of modification of a stent body. Since a fixed section of covering and a stent body is distributing to the whole stent body, this thing cannot be found to a part strongly [stress] at the time of use and detention, and there is also little danger of a fracture of covering in a fixed section.

[0027]As the cylindrical cover 3, as shown in drawing 2, what was beforehand formed in tubed is preferred, but what twisted a band-like thing around the stent body 2, and was formed in tubed as a whole may be used. Although what there is no terminal area in tube shape, and was formed as what was beforehand formed in tubed is preferred, a thing which rolled a band-like thing, carried out thermal melting arrival of the end, and was made tubed, and a thing which wound a band-like thing around a spiral and was made tubed may be used. In this example, what there is no terminal area in tube shape, and was formed of extrusion molding etc. is used.

[0028]As a formation material of the cylindrical cover 3, the thermoplastics 4 and a synthetic resin in which thermal melting arrival is possible are used suitably more highly [the melting point] than the thermoplastics 4. What has flexibility or elasticity is preferred more preferably. As for the melting point, it is more preferred than points, such as workability, that it is higher than not less than 20 ** and the above-mentioned thermoplastics 4. As an example of a formation material of the cylindrical cover 3, a fluoro-resin (for example, PTFE, ETFE), polyolefine (for example, polyethylene, polypropylene), polyester, thermoplastic polyurethane, etc. are used.

[0029]As the cylindrical cover 3, what is not contracted at the time of thermal melting arrival with a stent body is preferred. As a raw material (film) which is not contracted at the time of thermal melting arrival, what seldom has a heat history at the time of manufacture, a thing which is not extended at the time of manufacture, etc. can be considered. Before using as a cylindrical cover, it may correspond by using it, after making it contract by heating to temperature of a grade at the time of thermal melting arrival. As a cylindrical cover, a thing about 0.01-0.2 mm thick is preferred.

[0030]As the cylindrical cover 3, a porous membrane formed with the above synthetic resins is preferred. Since some thermoplastics which dissolved at the time of thermal melting arrival flows in membranous fine pores as by using a porous membrane shows to drawing 3, fixing strength of the thermoplastics 4 and the cylindrical cover 3 becomes high, and exfoliation at the time of use can be prevented certainly. As a void content of a porous membrane, about 25 to 80% of thing is preferred, and an about 0.1-10-micrometer thing is preferred for a pole diameter. If it is within the limits of the above-mentioned void content, there will be no problem in physical properties as a cylindrical cover. If it is within the limits of the above-mentioned pole diameter, there is also no invasion of a body tissue, and there is no problem also in the physical properties of a cylindrical cover, and an inflow of fused thermoplastics is also easy. As an example of a porous membrane, trade name pore chlorofluocarbon (made by Sumitomo Electric Industries, Ltd.) of a PTFE system, trade name micro textile (made by NITTO DENKO CORP.), trade name Gore-Tex (made in Gore-Tex Japan, Inc.), etc. can be used, for example. By using porosity, the film itself becomes very flexible, and it bends along with the crooked abdominal cavity, and extension power of stent is not affected. An outside surface of a cylindrical cover may be coated with a living body cell adhesion substance (for example, fibrous protein, such as collagen, keratin, and fibroin), a living body cell may be made to invade into the fine pores, and adhesion with a living body organ may be raised. Especially PTFE as generally used for a patch of an artificial blood vessel or a pericardium, It is known for inertness to a living body that biocompatibility is high, and a cylindrical cover is created using porosity of this PTFE, The outside surface may be coated with the above living body cell adhesion substances (for example, fibrous protein, such as collagen, keratin, and fibroin), and living body cell invasiveness into the fine pores may be raised.

[0031]As the cylindrical cover 3, not the above porous membranes but a thing of nonporous film state may be used, and a laminated film of two-layer structure in which one layer turned into a reinforcement layer and two-layer turned into a thermal melting arrival resin layer with the thermoplastics 4 may be used further. As a thermoplastic resin layer, above-mentioned thermoplastics can use it conveniently and a formation material of an above-mentioned cylindrical cover can use it conveniently as a reinforcement layer. Thermal melting arrival of the stent body 2 and the covering 3 covered with thermoplastics can be performed by, inserting a stent body with which thermoplastics was covered into a cylindrical cover for example, and forcing a rod heated to a cover part in contact with a stent body. Especially, when thermoplastics carries out below with the melting point of more than melting temperature and a covering formation material, temperature of a heating rod, Without making the covering itself produce thermal denaturation, can adhere covering to a stent body, covering is not made to

generate a closing-in part at the time of thermal melting arrival, and the physical properties of covering are not reduced selectively.

[0032]Although a cylindrical cover is adhered from the outside of a stent body in this example, what just blocked a side attachment wall of a stent body, inserted a cylindrical cover into a stent body, and adhered covering inside a stent body (inner surface side) may be sufficient as a cylindrical cover.

[0033]Next, stent of an example shown in drawing 4 is explained. Drawing 4 is a perspective view of other examples of stent of this invention, drawing 5 is an amputation stump side figure near the end of stent shown in drawing 4, and drawing 6 is the elements on larger scale of drawing 5. The stent body 12 in which the stent 10 of this example was formed in the shape of a cylindrical shape and whose diameter can be reduced, Are the cylindrical cover 13 which wraps a side attachment wall (side) of the stent body 12 entirely (blockade) the stent which it has, and the cylindrical cover 13, It consists of the inner surface side film 14 provided in an inner surface of the stent body 13, and the outside surface side film 15 provided in the outside surface side of the stent body 12, Either [at least] the inner surface flank film 14 or the outside surface side film 15 serves as a tube-like object, and further, while pinching the stent body 12 by between the inner surface side film 14 and the outside surface side film 15, both have adhered in a contact portion.

[0034]For this reason, the opening (hole) 12c and the notch 12d of the stent body 2 prevent a body tissue from being blockaded and invading in stent from the exterior. Since the cylindrical cover 13 is formed so that the stent body 12 may be pinched, the cylindrical cover 13 does not break away from a stent body, and it prevents separation with a stent body after the time of detention work of stent, and detention, and covering. Since the cylindrical cover 3 is formed so that the stent body 2 may be pinched, the flattery nature of modification of covering to modification of a stent body is high, and it is rare for covering to become an obstacle of modification of a stent body. Since a fixed section of an inside film and an outside film is distributing to the whole stent 1, this thing cannot be found to a part strongly [stress] at the time of use and detention, and there is also little danger of a fracture of covering in a fixed section.

[0035]The stent body 2 explained in the example mentioned above as the stent body 12 is used suitably. As shown in drawing 4, this stent body 12 has two or more notch or two or more openings which were formed in the side of a cylinder body like the stent body 2, and has a modification auxiliary function which assists modification to a direction whose diameter an outer diameter reduces at the time of stress load constituted by this. The stent body 12 has the notch 12d divided by the opening 12c divided by the frames 12a and 12b (****), and the frame 12a.

[0036]As shown in drawing 6, a layered product of the 1st resin layer 14a and the 2nd resin layer 14b formed with resin whose melting point is lower than the 1st resin layer formation resin is used for the outside film 14. Similarly the inner surface side film 15 is also a layered product of the 1st resin layer 15a and the 2nd resin layer 15b formed with resin whose melting point is lower than the 1st resin layer formation resin, That in which the 2nd resin layer 15b was formed with resin in which the 2nd resin layer 14b of the outside film 14 and thermal melting arrival are possible is used. And the outside film 14 and the inside film 15, As shown in drawing 4 thru/or drawing 6, where each other is faced, thermal melting arrival of both whole (the 2nd resin layer 14b and 15b that faces each other) contact portion is carried out, and the stent body 2 is in the state where it was embedded ɔetween the 2nd two resin layer 14b that turned about one body by thermal melting arrival, and 15b. Although it s preferred that thermal melting arrival of the whole contact portion is carried out, partial thermal melting arrival nay be sufficient.

[0037]What what has the 2nd resin layer formation material mentioned later and an adhesive property as the 1st resin layer 14a and 15a of the outside film 14 and the inside film 15 is used, and has flexibility or elasticity and is further provided with a certain amount of intensity is preferred. For example, a fluoro resin film (for example, PTFE, ETFE), a polyolefin film. (For example, a polyethylene film and a polypropylene film), a vinyl chloride resin film, An ethylene-vinyl acetate copolymer film, polyester film (for example, a polyethylene terephthalate film, an extension polyethylene terephthalate film), a thermoplastic polyurethane film, etc. can be used.

[0038]As the 1st resin layer, what is not contracted at the time of thermal melting arrival with a stent body is preferred. As a raw material (film) which is not contracted at the time of thermal melting arrival, what seldom has a heat history at the time of manufacture, a thing without heat contraction nature resulting from extension at the time of manufacture, etc. can be considered. It may correspond by using it, after making it contract before use by heating to temperature of a grade at the time of thermal melting arrival. As the 1st resin layer, a thing about 0.07-0.3 mm thick is preferred.

[0039]As the 2nd resin layer 14b and 15b of the outside film 14 and the inside film 15, there is an adhesive

property with the 1st resin layer formation material, and thermoplastics whose melting point is lower than the 1st resin layer formation material is used. As the 2nd resin layer, although low melting point polyolefine (for example, low density polyethylene, low density polypropylene), vinyl chloride resin, an ethylene-vinyl acetate copolymer, thermoplastic polyurethane, etc. can be used, optimal thing is polyolefine. As the 2nd resin layer, that whose melting point is about 120-200 ** is preferred, and it is more preferred than points, such as workability, that the not less than 20 ** melting point is lower than the 1st resin layer especially. About 10-100 micrometers is preferred for thickness of the 2nd resin layer.

[0040]As the inside film 14 and the outside film 15, as shown in drawing 4 and drawing 5, it is preferred that it is the tube-like object beforehand formed in tubed, but what twisted a band-like thing around the stent body 12, and was formed in tubed as a whole may be used. Although what there is no terminal area in tube shape, and was formed as what was beforehand formed in tubed is preferred, a thing which rolled a band-like thing, carried out thermal melting arrival of the end, and was made tubed, and a thing which wound a band-like thing around a spiral and was made tubed may be used. In this example, what there is no terminal area in tube shape, and was formed of extrusion molding etc. is used.

[0041]Although the same thing is used in this example, an outside film and an inside film, Either is the above two-layer laminated films at least, and the other may be formed with a resin film of not only this but the inner surface side film or the outside surface side film in which the 2nd resin layer and thermal melting arrival are possible. The inner surface side film and the outside surface side film, At least one side should just be a tube-like object, and another side, Regular-intervals alienation may be carried out mostly and a band form with two or more prescribed width provided in parallel with shaft orientations of the stent body 12 may be established, It may be a band form with prescribed width which regular-intervals alienation could be carried out mostly, an annular band form with two or more prescribed width provided so that it might intersect perpendicularly with shaft orientations of the stent body 12 could be established, and a predetermined angle had in shaft orientations of the stent body 12 further, and was twisted around spiral shape.

[0042]

[Example]Next, the concrete example of the stent of this invention is described.

(Example 1) The alloy pipe of the Ti Ni alloy (51 atom %nickel) was cold-worked, and a superelasticity metallic pipe the outer diameter of 8.2 mm, 7.6 mm in inside diameter, the thickness of 0.3 mm, and about 50 mm in length was created. The rod made from stainless steel the outer diameter of 7.6 mm and 100 mm in length was inserted in this, and this pipe and rod were fixed with adhesives. The rod portion was fixed to NC high-speed fraise machine SF44 by Makino Milling Machine Co., Ltd., the end mill (edged tool) with an outer diameter of 0.3 mm of the super-narrow diameter was set to the fraise machine, milling was performed in about 8,000-rpm high velocity revolution, and the stent body of shape as shown in drawing 1 was created. And in order to cut off the edge of the frame of the stent the corners, the glass bead with a particle diameter of 15-30 micrometers was used, and blast processing was carried out in pressure ^{2} of 2-3kg/cm. De-burring and camfering were performed by this blast processing.

[0043]the SEFURARU software by a central glass company (a registered trademark.) which is a thermoplastic fluorinated elastomer 7% dimethyl formaldehyde fluid with a melting point of about 162-165 ** is prepared, after the above-mentioned stent body is immersed in this, it pulls up, and it was made to dry and 140 ** of thin tunics of thermoplastics were made to form in all the surfaces of the stent body 12 for about 5 minutes. The thickness of the tunic was an average of 18 micrometers.

[0044]This was twisted around the outside of the stent body which has the above-mentioned thermoplastic resin film, using a porosity film (trade name pore chlorofluocarbon, the Sumitomo Electric Industries, Inc. make, 0.02 mm of thickness, 30% of a void content, the aperture of 0.5 micrometer, the melting point of 327 **) as a cylindrical cover formation material. And the rod heated at about 200 ** was forced on the portion in contact with a stent body, thermal melting arrival of the porosity film was carried out to the stent body, and formation and its adherence of the cylindrical cover were performed. Although the porosity film was carrying out opaque white for the existence of the usual fine pores, the rarefaction of the portion on which the heat rod was forced was carried out.This is because the thermoplastics which dissolved with heating invaded in fine pores. Thus, the stent of this invention was created. This stent is applicable to a strangulation improvement of an iliac artery, a femoral artery, and a bile duct.

[0045](Example 2) The same thing as Example 1 was used as a stent body. The 5% toluene solution of this thermoplastics was created using an ethylene-vinyl acetate copolymer (trade name URUTORASEN, the grade

680, the TOSOH CORP. make, melting point of 80 **) as thermoplastics. Pulled up, after the stent body was immersed in this solution, and it was made to dry in about 30 minutes at 60 **, and the thin tunic of thermoplastics was made to form in all the surfaces of a stent body. The thickness of the tunic was 15 micrometers.

[0046]As a cylindrical cover formation material, the porous polypropylene film (the Toyo Roshi Kaisha, Ltd. make, grade TCP, the pole diameter of 3 micrometers, 30% of a void content, thickness of 30 micrometers, melting point of about 130 **) was used. The porous polypropylene film was twisted around the outside of the stent body 2 which has the above-mentioned thermoplastic resin film. And the rod heated at about 100 ** was forced on the portion in contact with a stent body, thermal melting arrival of the porosity film was carried out to the stent body, and formation and its adherence of the cylindrical cover were performed. Thus, the stent of this invention was created. This stent is applicable to a strangulation improvement of an iliac artery, a femoral artery, and a bile duct.

[0047](Example 3) The same thing as Example 1 was used as a stent body. As the inner surface side film for forming a cylindrical cover, and an outside surface side film, a total (made by Toppan Printing Co., Ltd.) of the 27-micrometer laminated film of biaxial extension polyethylene terephthalate (12 micrometers in thickness, melting point of 250 **) and polyethylene (15 micro in thickness, melting point of 140 **) was used.

[0048]The round bar of the outer diameter a little smaller than a stent inside diameter was prepared, and it twisted around one layer so that the polyethylene side of the above-mentioned film might become outside at this. It twisted around one layer so that the stent might be inserted in on it and also the polyethylene side of the above-mentioned film might consist of on the inside. Then, the round bar was heated at not less than 100 **, it pushed with the rubber of the shape of soft sponge from the outside, and thermal melting arrival of the polyethylene layers was carried out. Although a stent body and polyethylene were not pasted up directly, thermal melting arrival of all the film (polyethylene layer which contacts) portions that contact is carried out, and the cylindrical cover in the state where the stent body was pinched was formed. Thus, the stent of this invention was created. This stent is applicable to a strangulation improvement of an iliac artery, a femoral artery, and a bile duct.

[0049]

[Effect of the Invention]The stent body in which the stent for detention of this invention in the living body was formed in the shape of a cylindrical shape, and two or more openings which open the outside surface and inner surface of this cylindrical shape for free passage were formed and whose diameter can be reduced, It has a thermoplastic resin layer which covers this stent body, and the cylindrical cover which adhered to this thermoplastic resin layer while covering the periphery and/or inner circumference of this stent body and plugging up this opening. For this reason, the free passage portion formed in stent side attachment walls, such as an opening of a stent body and a notch, is that which is blocked with covering, and a body tissue prevents invading in the stent from the exterior. The cylindrical cover has adhered to thermoplastics.

A cylindrical cover does not exfoliate from a stent body and separation of both after the time of the detention work of the stent and detention is prevented.

Since the cylindrical cover has adhered in the whole contact portion (contact portion with thermoplastics) with a stent body, Since the flattery nature of modification of covering to modification of a stent body is high, it is rare for covering to become an obstacle of modification of a stent body and the fixed section of covering and a stent body is distributing to the whole stent body further, This thing cannot be found to a part strongly [stress] at the time of use and detention, and there is also little danger of a fracture of covering in a fixed section.

[0050]The stent for detention of this invention in the living body is stent provided with the stent body in which it was formed in the shape of a cylindrical shape, and two or more openings which open the outside surface and inner surface of this cylindrical shape for free passage were formed and whose diameter can be reduced, and the cylindrical cover which plugs up this opening and wraps this stent body entirely.

The inner surface side film with which said cylindrical cover was provided in said stent body inner surface, It consisted of an outside surface side film provided in the outside surface side of said stent body, and at least one side of this inner surface side film and this outside surface side film serves as a tube-like object, and said stent body was further pinched between this inner surface side film and this outside surface side film, and it has adhered through this opening.

For this reason, even if openings (communicating part of the inside of the stent and the exterior), such as an opening and a notch, exist in the side attachment wall of a stent body, since it is blockaded with covering, they prevent a body tissue from invading in the stent from the exterior. Since the cylindrical cover is formed so that a

stent body may be pinched, a cylindrical cover does not break away from a stent body, and it prevents separation with the stent body after the time of the detention work of the stent, and detention, and covering. Since the cylindrical cover is formed so that a stent body may be pinched, the flattery nature of modification of covering to modification of a stent body is high, and it is rare for covering to become an obstacle of modification of a stent body. Since the fixed section of an inside film and an outside film is distributing to the whole stent body, this thing cannot be found to a part strongly [stress] at the time of use and detention, and there is also little danger of a fracture of covering in a fixed section.

[Translation done.]